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UNCLAS ZAGREB 001836

SIPDIS

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STATE FOR USTR

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SUBJECT: IMPLEMENTATION OF IP MOU STALLS: EC NOT THE REASON, BUT A GOOD EXCUSE

REF: ZAGREB 387

SUMMARY AND COMMENT

11. (SBU) The GOC has not yet taken action on legislative changes need to implement and bring into force the Intellectual Property MOU, finally ratified in March, despite Ministerial-level reassurances in September. European Commission officials have raised open-ended questions about the MOU in meetings with GOC officials, but EU ambivalence is not why its implementation has stalled. Rather, our allies, notably in the Ministry of Foreign Affairs, have to push for the MOU over the objections of a strong Minister of Health and a strong domestic lobby. Once the EU gets data exclusivity protection -- required by its Interim Agreement with Croatia and also a small but important part of the MOU -- and as Croatia begins negotiations on accession early in 2005, we expect EU griping about the MOU to become even louder. End Summary and Comment.

Amendments Blocked

12. (SBU) The Ambassador has repeatedly pressed the government -- most recently in mid-September -- to move forward two pieces of legislation to enable the 1998 MOU to come into force: one amends the drug law to provide data exclusivity and the other amends the patent law to provide "pipeline protection" (a one-year window in which companies can file for patents on products not yet on the market but which are past the usual period for filing). Two ministers assured the Ambassador that one or both pieces of legislation would be on the government's agenda before the end of September. In several government sessions held since then, however, the issue was not considered.

13. (SBU) Government and industry contacts report that the local generics industry and the Minister of Health (and Deputy Prime Minister for Economy) Andrija Hebrang oppose the MOU. Hebrang is wrestling with an enormous budget gap in the public health system, and the U.S. industry believes he extracted large pricing concessions from local generics manufacturers in partial exchange for delaying the introduction of data exclusivity. In the meantime, our industry informs us that a bumper crop of marketing requests for locally-produced generics, which rely on U.S. test data for registration, are being approved and the copied drugs are being put on the drug reimbursement list.

EC Innocent... Sort Of

14. (SBU) In late September, Globus (a sensationalist but occasionally accurate weekly) published a titillatingly titled article, "Barroso and Sanader in Conflict Over Viagra." The article claimed that the European Commission had written to PM Sanader opposing the MOU. The EC Delegation confirmed that no such letter existed. In fact, the EC had recently reminded the Minister of European Integration of the need to get cracking on data exclusivity, and complaining of long drug registration periods. However, our EC counterpart told us that the EC "was not overjoyed with the prospect of the MOU." She did not provide an explanation other than exasperation that Croatia did not discuss or share the MOU with the Commission before it was ratified."

15. (SBU) The MFA has confirmed that the EC Delegation had recently made informal remarks in meetings with GOC officials indicating "serious questions" about the MOU. Head of the North America Desk at the MFA -- a supporter of the MOU -- said, "Frankly, these comments make our job harder. Some clarity would be appreciated."

16. (SBU) Econoff met with visiting EC staffers on October 18, including Alain Deckers from the Commission's

Internal Market DG. The officials said that they had no objections to the two pieces of legislation as long as they were non-discriminatory and did not prevent Croatia meeting its obligations under the Interim Agreement. We shared frustration that the Ministry of Health was telling each of us that the other was an obstacle to devising data exclusivity language.

17. (SBU) Deckers did note that Croatia would have to

"denounce" some parts of the MOU upon EU entry, for procedural rather than substantive reasons. Other parts of the MOU, notably in the copyright area, might not conform to EU Directives, but he was not able to give details. The Commission's Croatia Desk Officer went further, saying that he was sure that the U.S. would not want to do anything to complicate Croatia's accession and implying that the MOU could cause problems. Econoff asserted that bringing the MOU into effect was not negotiable and noted that the mixed signals being sent about the MOU were being used by those who wanted to block data exclusivity and pipeline protection, which hurts us both.

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